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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,830	12/28/1999	JEFFREY M. LEIDEN	2844/53802	1518

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HALE AND DORR LLP  
300 PARK AVENUE  
NEW YORK, NY 10022

EXAMINER
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CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 03/07/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/473,830

Applicant(s)

LEIDEN ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Applicants' response filed 1-2-02 has been entered. No claims have been amended, canceled or added. Claims 24-46 are pending and under consideration.

#### *Claim Objections*

1. Claim 24 is objected to because of the following informalities: The phrase "perfused by said artery or said sinus" in line 5 is vague. It is unclear how the cardiomyocytes "perfused by" the artery or sinus. Changing the phrase "perfused by said artery or said sinus" to "perfused **through** said artery or said sinus" would be remedial. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 24-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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As discussed in the preceding Official action, the claims are directed to gene therapy *in vivo* in light of the specification. Gene therapy *in vivo* is the sole use for the claimed method in light of the specification. The specification must provide enabling disclosure for the method of infusing a recombinant rAAV vector expressing any desired molecule into a coronary artery or a coronary sinus so as to provide sufficient expression of said desired molecule in cardiomyocytes and elicit therapeutic effect for a variety of cardiovascular disease and conditions in a patient. The official action mailed 8-29-01 (Paper No. 15) does not reject the enablement of transducing cardiomyocytes by using a rAAV vector via infusing said rAAV into a coronary artery, rather the Official action provides explanation why the specification fails to provide enabling disclosure for *in vivo* gene therapy via introduction of a rAAV vector expressing any desired molecule into cardiomyocytes so as to provide therapeutic effect for a variety of cardiovascular disease and conditions in a patient in light of the specification of the present application. The working example provided in the specification, i.e. expression of beta-gal in cardiomyocyte *in vivo*, does not enable therapeutic use of rAAV vector expressing any desired molecule for gene therapy *in vivo*. The working embodiment of the specification fails to provide a use for gene therapy *in vivo* and does not meet the requirement of 35 U.S. 101 because the lacZ embodiment is not taught to be useful in therapy, and the specification does not assert any specific or substantial utility for this specific embodiment nor does the evidence of record suggest a well-established utility for this specific embodiment. Consequently, this embodiment does not meet the requirement of 35 U.S.C. 101 and the how to use requirement of 35 U.S.C. first paragraph.

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Applicants argue that the specification enables a method of transducing cardiomyocytes by infusing a recombinant adeno-associated virus (AAV) vector comprising a nucleic acid expressing a desired molecule into a coronary artery or a coronary sinus and the Official action does not provide explanation for the enablement rejection of the claimed invention. Applicants further argue that the Official action only rejects the unclaimed subject matter, i.e. gene therapy (response, p. 9-12). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 8-29-01 (Paper No. 15) and the reasons set forth above.

### ***Conclusion***

No claim is allowed.

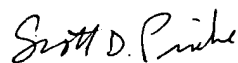
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



**SCOTT D. PRIEBE, PH.D**  
**PRIMARY EXAMINER**

Shin-Lin Chen, Ph.D.